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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,126	10/28/2003	Richard L. Antrim	006401.00433	6117

22908 7590 03/24/2008

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EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,126	ANTRIM ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/31/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim 1-4 are pending and under examination.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 1/31/08.

NEW GROUNDS OF REJECTION

The following new grounds of rejection are made against claims 1-4.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boskovic et al. (US 5,124,162; cited in the Office Action mailed 7/3/07) in view of Tang et al. (US 5,854,487; new reference) and Rohrbach et al. (US 4,511,654, cited in the IDS filed 3/23/05).

Boskovic discloses an antioxidant-free, stable fixed flavor which is prepared by combining a flavor, maltose, maltodextrin and a film former to make a mixture and then spray-drying the mixture to form a dense product (abstract). Boskovic provides disclosure relating to the relative amounts of maltose and malto-dextrin, as well as the preferred DE range for the latter (col. 6, lines 9-30). The step of instant claim 1 relating to providing an amount of a dextrin to enhance the susceptibility of the maltose-containing product to be spray-dried is considered to be a mental step in the absence of any physical steps to determine this optimization. Hence, Boskovic meets these

limitations because the disclosure of the desired relative amounts of maltose and maltodextrin are provided to optimize the spray-drying qualities of the mixture to form the desired dense product.

Boskovic does not disclose a maltodextrin carrier is prepared by treating starch with a beta-amylase wherein retrograded amylose is produced and at least some of the retrograded amylose is separated via ultrafiltration wherein the resulting product has a DP<10; or the starch is liquefied with an alpha-amylase prior to beta-amylase treatment.

Tang discloses that it is desirable to employ nanofiltration to enzyme- or acid-hydrozylates of starch to remove retrograded amylose an to obtain a low DE hydrozylate blend. Such products are substantially retrograde-product free and have a very low viscosity. Low DE products that lack retrograded amylose are particularly suited for spray-drying (abstract and col. 3, lines 63-68 to col. 4, lines 1-13).

Rohrbach discloses a process for producing a maltodextrin wherein starch is liquefied by alpha-amylase, the product removed from the alpha-amylase and then subjected to hydrolysis with a column-immobilized beta-amylase. The temperature of hydrozylate is held at 22 degrees C and then subjected to ultrafiltration. The low temperature will necessarily cause retrograded amylose to precipitate and ultimately removed by the filtration step (see Ex. III at col. 10, lines 1-44). Rohrbach discloses that using an Amicon UM2 filter resulted in a product having 9.7% DP3 oligosaccharide and 0.2% of a DP9+ oligosaccharide. Hence the total DP is 9.9% (col. 10, lines 32-36) which is less than the 10 recited by claim 1. Rohrbach does not disclose the DE of the filtered hydrozylate products. However, it is disclosed at col.3, lines 42-47 that that alpha-amylase is employed to adjust the DE of the pre-beta-amylase hydrolyzed slurry to about 5-25. The examples employ an alpha-amylase adjusted slurry having a DE of 15. In Ex. III, Rohrbach discloses that the

DE of the alpha-amylase adjusted slurry can be adjusted according to the desired level (col. 10, lines 5-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a low DE starch that has been hydrolyzed by alpha-amylase and beta-amylase followed by the filtration of retrograded amylose as a carrier for spray-drying maltose containing products. The ordinary artisan would have been motivated to do so becasue Tang specifically recommends that enzyme-hydrolyzed starch which have been subjected to retrograded amylose removal are very desirable for spray drying due to their very low viscosity. The ordinary artisan would have had a reasonable expectation that the method of producing a maltodextrin according to Rohrbach (e.g., treatment of starch by alpha-amylase and beta-amylase followed by the filtration of retrograded amylose) would suit the spray-drying method disclosed by Boskovic because it has reduced retrograded amylose content as recommend by Tang and has a DE at least less than 25% that can be adjusted as needed according to Rohrbach.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaper et al. (US 4,780,149) and Rohrbach et al. (US 4,511,654), both cited in the IDS filed 9/23/05).

Kaper discloses the preparation of a maltose/ β -limit dextrin composition by contacting starch with β-amylase, followed by α-amylase treatment, and precipitation of the retrograded amylose and separation from the β-dextrin/maltose-containing solution by centrifugation or filtration. See column 1, lines 44-52; and in particular column 3, lines 1-25 discussing the embodiment wherein the precipitated amylose is removed from the dextrin and maltose-containing solution. Note further that the process is recited in open "comprising" language, which

encompasses the additional steps recited in the reference. Kaper teaches that the disclosed maltose/ β-limit dextrin composition is useful in food and pharmaceutical products and that β-limit dextrins can also be used as a carrier of dried liquids such as fruit juices, etc. (col. 3, lines 26-39). Therefore, the spray-drying of the disclosed maltose/ β-limit dextrin composition with fruit juice to make a powder meets the corresponding claim limitation since the mixture to be sprayed comprises a maltose/ β-limit dextrin composition.

Kaper discloses that the DE of the maltose/ β-limit hydrozylate is about 5-30 and that the alpha amylase treatment should result in a product wherein the DE of the starch hydrozylate is increased by no more than 3 units. Thus, the DE of the final hydrozylate is 8-33 which corresponds to a DP range of 3 to 12.5 (DE=100/DP) which overlaps the claimed DP range of less than 10.

It is still further noted that the claims recite the enzyme composition as one "consisting essentially of" β-amylase. It is also noted that the process of Kaper uses α-amylase in addition to β-amylase. However, MPEP § 2111.03 clearly states that "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." (Citations omitted, emphasis in original.) Moreover, MPEP § 2111.03 states that claims recited in "consisting essentially of" language should be construed as if recited in open "comprising" language, absent some evidence that the additional ingredients in the prior art process/product materially affect the basic and novel properties of the claimed invention:

> For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG* [*Industries v. Guardian Industries*], 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its

> patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963).

On the current record there is no evidence that the α-amylase would affect the basic and novel properties of the prior art process such that the prior art process is truly different than the claimed process. Thus, applicant's claims must be construed as if reciting "comprising" language, thereby encompassing the additional ingredients in the prior art process, despite the "consisting essentially of" language. A holding of anticipation/obviousness is therefore required.

Lastly, note specifically that MPEP 2111.03 further provides that "[w]hen an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention." (Citations omitted.)

Kaper does not teach that the retrograded amylose is removed by ultrafiltration.

Rohrbach discloses a process for producing a maltodextrin wherein starch is liquefied by alpha-amylase, the product removed from the alpha-amylase and then subjected to hydrolysis with a column-immobilized beta-amylase. The temperature of hydrozylate is held at 22 degrees C and then subjected to ultrafiltration. The low temperature will necessarily cause retrograded amylose to precipitate and ultimately removed by the filtration step (see Ex. III at col. 10, lines 1-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to remove retrograded amylose in the starch hydrozylate taught by Kaper by ultrafiltration.

The ordinary artisan would have been motivated to do so because Rohrbach successfully achieved the removal of retrograded amylose by this method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/

Examiner, Art Unit 1651

/Sandra Saucier/

Primary Examiner, Art Unit 1651